DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

August 6, 1999

WARNING LETTER NYK 1999-60

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard W. Seeley, Co-Owner
Unique Health Solutions
1007 Green Street
Utica, New York 13502

Dear Mr. Seeley:

This letter is in reference to your firm's marketing and distribution of the product, MSM Eye and Ear Drops. Labeling for this product contains therapeutic claims which cause the product to be a drug [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. Labeling is not limited to the immediate product container but includes all promotional literature which you distribute in connection with your product.

Objectionable claims include: "cataracts", "glaucoma", "softens the membranes allowing fluids to pass through the optical tissue", "equalizes pressures, repairs damaged membranes, clears up red spots and broken vessels, helps remove floaters and other eye particles", and "contact lens users have reported that the drops are better than saline solution... provide soothing, lasting relief".

This product is a "new drug" [Section 201(p) of the Act]. Therefore, it may not be legally marketed in this country without an approved New Drug Application [Section 505(a) of the Act].

This drug is also misbranded because its labeling fails to bear adequate directions for the conditions for which it is offered [Section 502(f)(1) of the Act] and its labeling is false and misleading. The labeling suggests that this product is safe and effective for its intended use, when in fact, this has not been established [Section 502(a) of the Act].

Additionally, this product is subject to the final rules (monographs) on "Ophthalmic Drug Products for "Over-The-Counter Human Use" and "Topical Otic Drug Products for Over-The-Counter Use". The monographs are found in Title 21 Code of Federal Regulations (21 CFR) Parts 344 and 349. Neither the formulation nor the labeling for the product conform to these final regulations.

This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

Further, promotional materials for Calorad titled, "Calorad, A Product For Life", include claims that the product can reduce the risk of cancer, heart disease and diabetes, and can treat pneumonia. Promotional materials for MSM caplets and lotion titled, "The People's Choice, MSM Premium Plus", contain a number of therapeutic treatment claims including: allergies, asthma, parasites, salmonella, giardia, cryptosporidium, arthritis, yeast infections, chronic fatigue, snoring disorders, muscle damage, pain relief from burns, Carpal Tunnel Syndrome, insect bites, and anti-venom from snake and spider bites. Promotional materials titled, "Want to Feel Good Again Try Some MSM" include: "increase the body's ability to produce insulin to the point where insulin injections can be reduced", ulcers, "control of hyperacidity... chronic users of antacids and histamine H_2 receptor blockers", and "hypersensitivity to drugs".

We are also aware that your firm's Internet web site lists therapeutic claims for the MSM Eye and Ear Drops and for additional products. Such claims may also cause these products to be misbranded drugs. These additional products include:

- CareCardia..... Preventing and reversing coronary artery blockage, heart attack, angina
- L'Aprina..... Analgesic, anti-inflammatory, TMJ, Shingles, Fibromyalgia, arthritis, bursitis, joint-pain, transdermal action
- Bovine Colostrum ..... Immune deficient, attack invading bacteria, viruses, allergens and fungi, neutralize poisonous toxins
- Smoker's Freedom System ..... Diminish the desire to smoke, control sudden urges to smoke, headaches
- Sleep-A-Weigh..... Obesity, cancer

Additionally, the claims for Smoker's Freedom System cited above cause it to be subject to the final monograph, "Drug Products Containing Active Ingredients Offered Over-the-counter (OTC) for Use as a Smoking Deterrent" (21 CFR 310.544). Neither the formulation nor the labeling for the product conform to this final regulation.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Lisa M. Utz, Compliance Officer, at the above address. If you have any questions, Ms. Utz can be reached at (716) 551-4461, ext. 3165.

Sincerely,

Brenda J. Holman
District Director